

## REMARKS

### 1. Formal Matters

#### a. Status of the claims

Claims 21, 23, 25, 28, 29, and 32-45 are pending in this application. Claim 21 is amended, and claims 46-52 are new. Claims 22-45 are canceled solely to expedite prosecution and without prejudice to seeking claims of similar scope in a continuing application. Upon entry of these amendments, claims 21, and 46-52 are pending and at issue. Applicant respectfully request entry of the foregoing amendments to place the application in condition for allowance or a better form for appeal.

#### b. Interview Summary

The undersigned would like to thank Examiner Vivemore and Examiner Zara for the courtesy of the interview of May 8, 2007 during which support for the claimed subject matter was discussed. This Reply is filed to address the issues raised by the Examiner, and is believed to place the application in condition for allowance.

#### c. Amendments to the claims

Previous claim 21 recited SEQ ID NO: 37404, which is a hairpin comprising the miRNA sequence set forth in SEQ ID NO: 37405. For the convenience of the Examiner, Appendix A shows the relationship of the hairpin and the miRNA.

Amended claim 21 now relates to the miRNA sequence set forth in SEQ ID NO: 37405. The length of the nucleic acid is X nucleotides, wherein  $X \geq 18$  to 24. Support for this length can be found in claim 1 as originally filed, which recites "said bioinformatically detectable novel viral gene is about 18 to about 24 nucleotides in length."

Part (a) of claim 21 relates to sequence of the nucleic acid that may comprise a sequence with Y consecutive nucleotides of SEQ ID NO: 37405, wherein  $Y \geq 18$  and  $X \geq Y$ . Support for part (a) of claim 21 can be found in originally filed claim 1 as described above.

Part (c) of amended claim 21 relates to a sequence at least 62.5% identical to (a) or (b), support for which can be found at Table 2 as originally filed. Table 2 shows that 15 out of 24 (62.5%) nucleotides of the miRNA related to SEQ ID NO: 37405 are sufficient to target the binding site of ATP6V1F as follows:

GENE	TARGET	UTR	SEQUENCE	SEQID	BINDING-SITE
GAM1483	ATP6V1F	3'	TGGCAAGCCTGGGGAGAG	37408	<div style="display: flex; justify-content: space-around;"> <div> A TG CAAGCCTG          AC GTTCGGAC C </div> <div> AC GAGAG     CTCTC CC </div> </div>

New claim 46 relates a nucleic acid comprising the miRNA sequence as set forth in SEQ ID NO: 37405. The length of nucleic acid is X nucleotides, wherein X=50 to 120 nucleotides. Support for this length can be found at paragraph 0014 of the specification as originally filed. Paragraph 0014 recites in part, "RNA precursor is about 50 to 120 nucleotides in length..." New claim 46 also recites that the sequence of the nucleic acid comprises Y consecutive nucleotides of SEQ ID NO: 37405, wherein Y $\geq$ 18 and X>Y, support for which can be found as described above for amended claim 21.

New claims 47 and 48 relate to a nucleic acid of claim 21 or 46, wherein (c) is a sequence at least 75% identical to (a) or (b), support for which can be found a Table 2 as originally filed. Table 2 discloses that 18 out of 24 (75%) nucleotides of the miRNA related to SEQ ID NO: 37405 are sufficient to target the binding site of DUSP5 as follows:

GAM1483	DUSP5	3'	TGCAAGCCTGGTGACCACCTCA	37407	<div style="display: flex; justify-content: space-around;"> <div> A TG CAAGCCTG          AC GTTCGGAC — </div> <div> ACGA GA CGTTCA          CT GTGAGT CA_ G </div> </div>
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New claims 49 and 50 relate to a nucleic acid of claim 21 or 46, wherein (c) is a sequence at least 83.4% identical to (a) or (b), support for which can be found at Table 2 as originally filed. Table 2 discloses that 20 out of 24 (83.4%) nucleotides of the miRNA related to SEQ ID NO: 37405 are sufficient to target the binding site of MIC2L1 as follows:

GAM1483	MIC2L1	3'	GACAAGCCTGACAAAGTTCA	37412	<div style="display: flex; justify-content: space-around;"> <div> GACAAGCCTGACGAG         CTGTTCGGACTGTTT </div> <div> AGC GTTCA       CAAGT </div> </div>
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New claim 53 is related to a nucleic acid consisting of 18 to 24 nucleotides of SEQ ID NO: 37405, an RNA equivalent, a sequence at least 62.5%, 66.7%, 75%, and 83.4% identical thereto, or the complement thereof. New claim 53 is also related to a nucleic acid consisting of 50 to 120 nucleotides of SEQ ID NO: 37405, an RNA equivalent, a sequence at least 62.5%, 66.7%, 75%, and 83.4% identical thereto, or the complement thereof. New claim 53 recites the

nucleic acid of claims 21, 46, 47, 48, 49, or 50 wherein  $X = Y$ , antecedent basis and support for which can be found as described above for amended claim 21 and new claim 46.

New claim 52 recites a vector comprising the nucleic acid of claim 21, 46, 47, 48, 49, or 50, support for which can be found at paragraph 0023 of the specification as originally filed. Paragraph 0023 recites “the invention includes a vector including the DNA.”

## **2. Patentability Arguments**

### **a. Objections to the Claims**

At page 4 of the office action, the Examiner objects to claims 29, 33, 43, and 45 as being substantial duplicates of claims 21, 23, 40, and 41, respectfully. As discussed above, claims 22-45 have been canceled without prejudice. With regard to new claims 46-54, Applicant submits these claims are not duplicative of claim 23. In view of the foregoing amendments, Applicant respectfully submits that the objection of claims 29, 33, 43, and 45 is moot, and respectfully requests reconsideration and withdrawal of the objection.

### **b. Rejection Pursuant to 35 U.S.C. §112, First Paragraph**

At pages 5 and 6 of the office action, the Examiner rejects claims 21, 23, 25, 28, 29, and 32-39 under 35 U.S.C. § 112, first paragraph, for allegedly lacking written descriptive support from the specification. Specifically, the Examiner asserts that the limitation “at least 80% identical” is not supported by paragraphs 20 and 22, and that there is nothing in the specification as filed that would convey to one of skill in the art that applicant contemplated the limitation. Applicant respectfully disagrees.

With regard to new claims 47-52, Applicant respectfully submits that the common structural attributes required of the claimed miR variants are disclosed in paragraphs 0118-0120 and Figure 7 of the application as originally filed. Specifically, paragraph 0118 discloses that the sequence of miRNA may be partially complementary to the target binding site, thus clearly indicating that the disclosed miRNAs are capable of binding their targets with less than 100% complementarity.

Table 2 of the specification provides specific examples of the degree of complementarity sufficient for target site binding by the claimed miR. For example, the claimed miRNA is capable of binding a number of target binding sites with 15 complementarity nucleotides out of 24 (62.5%):

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GAM1483  ATP6V1F    3'  TGGCAAGCCTGGGGAGAG    37408      A          AC
                    TG  CAAGCCTG  GAGAG
                    ||  |||||
                    AC  GTTCGGAC  CTCTC
                        C          CC

GAM1483  DRF2P564C103 3'  TGATGGCCTGACGCTCTCTTCA 37409      CAA          AGAGCG
                    TGA  GCCTGACG  TTCA
                    |||  |||||
                    ACT  CGGACTGC  AAGT
                        AC_          GAGAG_

GAM1483  KIAA0935   3'  TGGCAAGCCTGGCAGGCG    37411      A          A G A
                    TG  CAAGCCTG  C AG GC
                    ||  |||||
                    AC  GTTCGGAC  G TC CG
                        C          C _ C

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These alignments indicate that the miRNA sequence can vary at different positions and still bind particular target binding sites. Examples of 75% and 83.4% complementarity between the miRNA and target binding sites are also described above. Accordingly, Applicant submits that one of skill would recognize through the teachings of the specification (e.g., Table 2) that Applicant was in possession of a number of miRNA species with at least 62.5% complementarity between the claimed miRNA and its target mRNAs. In view of the foregoing amendments and remarks, Applicant respectfully requests that the Examiner reconsider and withdraw the rejection of claims 21, 23, 25, 28, 29, and 32-39 under 35 U.S.C. § 112, first paragraph.

### 3. Conclusion

Applicant respectfully submits that the instant application is in good and proper order for allowance and early notification to this effect is solicited. If, in the opinion of the Examiner, a telephone conference would expedite prosecution of the instant application, the Examiner is encouraged to call the undersigned at the number listed below.

Respectfully submitted,

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Dated: May 22, 2007

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